EXHIBIT 5

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

RAVGEN, INC., Plaintiff, v. ILLUMINA, INC. AND VERINATA HEALTH, INC., Defendants.	Civil Action No. 20-1644-RGA-JLH **JURY TRIAL DEMANDED**
RAVGEN, INC., Plaintiff, v. ARIOSA DIAGNOSTICS, INC., ROCHE SEQUENCING SOLUTIONS, INC., ROCHE MOLECULAR SYSTEMS, INC., AND FOUNDATION MEDICINE, INC., Defendants.	Civil Action No. 20-1646-RGA-JLH **JURY TRIAL DEMANDED**
RAVGEN, INC., Plaintiff, v. BIORA THERAPEUTICS, INC., Defendant.	Civil Action No. 20-1734-RGA-JLH **JURY TRIAL DEMANDED**

LETTER TO THE HONORABLE JENNIFER L. HALL REGARDING DEFENDANTS' REQUEST FOR LEAVE TO AMEND THEIR ANSWERS AND COUNTERCLAIMS

Dear Judge Hall:

Defendants[1] respectfully move for leave to amend their Answers to add inequitable conduct counterclaims/defenses; and (for Biora, Roche, and FMI) to add release/license defenses based on the Agreement between Ravgen and Biora/Roche/FMI supplier Thermo Fisher (the "Ravgen-TF PLA"). The deadline to amend pleadings has not passed, leave to amend is "freely granted" under Rule 15(a), and no exception to this liberal standard applies here. Ravgen's only basis for opposing is supposed futility, but the amendments are not futile. To the contrary, when presented with these same defenses in another suit, the court: (1) ***denied*** Ravgen's motion for summary judgment of no inequitable conduct and scheduled an inequitable conduct bench trial before any jury trial; and (2) ***granted*** summary judgment that the Ravgen-TF PLA released a similarly situated TF customer.

A. Well-Pleaded Facts Relevant to Inequitable Conduct.

As set forth in detail in the proposed amended pleadings, Ravgen obtained the asserted patents by knowingly failing to disclose material information to the PTO with the intent to deceive:

- During prosecution, the PTO rejected numerous proposed claims stating that, ***absent any unexpected results***, the claims would have been prima facie obvious. Ex. 1, ¶¶ 26, 31, 33, 84.[2] Ravgen responded by arguing that experimental test results (included in the applications) showed purported "significant" and "unexpected" results of the alleged inventions. *Id.* ¶¶ 27-29, 85-87. Following Ravgen's "unexpected results" arguments, the PTO reversed its rejections and allowed the claims, specifically citing to Ravgen's arguments. *Id.* ¶¶ 27-36, 88; *see id.* ¶¶ 30, 50, 102 (Examiner referring to the unexpected results and related long-felt need arguments as the "***most persuasive argument(s)***" submitted).
- But ***at the same time*** they were relying on these supposedly "significant" and "unexpected" results to persuade the Examiner to allow the claims, named inventor Dr. Dhallan and Ravgen in-house counsel Dr. Cronin were aware—but failed to disclose—that well-known laboratories (led by Drs. Chinnapapagari and Chung) had published studies criticizing the accuracy and credibility of Ravgen's supposedly "significant" and "unexpected" experimental test results. *Id.* ¶¶ 37-47, 89-99. One article even described "***signs of inaccuracy, skewed data distribution, and analytical imprecision***" in Ravgen's work. *Id.* ¶¶ 41, 93. Following these articles, and still during prosecution, multiple scientists expressed concerns—directly to Drs. Dhallan and Cronin and in letters to the medical community that they received—about the test results and the failure to address the "controversy" around them. *Id.* ¶¶ 43-46, 95-98.
- Despite full knowledge of this extensive criticism of their test results, and despite the fact that it directly contradicted the arguments they were then making to the Examiner, Drs. Dhallan and Cronin failed to disclose any of the criticism, including the contradictory test results, to the Examiner. The only reasonable inference from the evidence is that Drs. Dhallan and Cronin

[1] "Defendants" are Biora Therapeutics, Inc. ("Biora"); Ariosa Diagnostics, Inc., Roche Sequencing Solutions, Inc., and Roche Molecular Systems, Inc. (collectively, "Roche"); Foundation Medicine, Inc. ("FMI"); and Illumina, Inc. and Verinata Health, Inc. (collectively, "Illumina").

[2] For purposes of this Motion, Defendants cite to Biora's proposed amendment, Ex. 1. Clean and redline proposed amended pleadings for each Defendant are attached as Exs. 1-8. Biora also seeks to add an unclean hands defense, and Roche and FMI seek to add patent exhaustion, prosecution history estoppel and equitable estoppel/unclean hands defenses. Emphases are added unless noted.

had a specific intent to deceive the PTO. *Id.* ¶¶ 47-52, 99-104.

When presented with the evidence, another court ***denied*** Ravgen's motion for summary judgement that the asserted '277 patent is not unenforceable, noting that the "evidence suggests the Examiner ***would have benefitted*** from knowing that like-minded people in the field faulted Dr. Dhallan for failing to address the 'controversy' between his results and the conflicting data." Ex. 9, *Quest*, D.I. 449 at 13.[3] He then scheduled a bench trial on inequitable conduct ahead of any jury trial.

B. Well-Pleaded Facts Relevant to Contract-Based Defenses.

Pursuant to the Ravgen-TF PLA—which is available in the public record—Ravgen has released Biora, Roche, and FMI from claims for past infringement of the asserted patents. Ex. 1 at 35-36; Ex. 3 at 24-26; Ex. 5 at 24. Specifically, the Ravgen-TF PLA defines "[TF] Released Parties" to include "past, current and future … end use and non-end use ***customers, purchasers and/or end users of any Covered Products***, but solely to the extent of their import, purchase, possession, use or resale of Covered Products directly or indirectly from [TF] or its Affiliates," where "Covered Products" means "***any*** [TF] or [TF] Affiliate product." Ex. 1 at 35-36.

Biora, Roche, and FMI purchased and used products from TF to perform the accused tests. *See id.* at 36. Each Defendant thus qualifies as a "[TF] Released Party" under the Ravgen-TF PLA. *Id.* Under Section 2.2 of the Ravgen-TF PLA, "Ravgen … ***irrevocably, unconditionally, absolutely and forever, releases***, acquits and discharges the [TF] Released Parties from any claim … for ***any alleged past infringement of the Ravgen Licensed Patents*** prior to the [June 23, 2021] Effective Date of this Agreement, or for any acts that might be deemed infringement of the Ravgen Licensed Patents," which include the asserted patents. *Id.* Other provisions address license grants (under which certain Defendants add a patent exhaustion defense).

While this case was stayed, the *Quest* court granted summary judgment that the Ravgen-TF PLA released a similarly situated TF customer from infringement claims because it (like Biora, Roche, and FMI) used TF products to perform accused tests. Ex. 9, *Quest*, D.I. 449 at 7.[4]

C. The Proposed Amendments Should Be Allowed.

Leave to amend is "freely" granted unless: (1) there is undue delay on the part of the moving party; (2) the amendment would unfairly prejudice the opposing party; (3) the amendment is brought in bad faith; or (4) the amendment would be futile. *Foman v. Davis*, 371 U.S. 178, 182 (1962); Fed. R. Civ. P. 15(a)(2). None of those exceptions applies here.

First, Defendants' Motion comes more than four months before the deadline to amend pleadings. *Invensas Corp. v. Renesas Elecs. Corp.*, 2013 WL 1776112, at *3 (D. Del. Apr. 24, 2013) (seeking leave before deadline "strongly supports a conclusion that the amendment [is] not untimely"). Defendants also had good reason not to seek leave sooner, as they learned factual bases for their

[3] The proposed amendments also show that Ravgen misrepresented to the Examiner that Ravgen's technique resulted in fetal DNA percentages of "***100%***" when it did not actually achieve 100%—Ravgen instead admits it merely "***represented***" its results as 100%. Ex. 1, ¶¶ 57-60, 109-112.

[4] Biora stopped performing the accused tests around the time of the effective date of the Ravgen-TF PLA, so the release defense alone could be essentially case dispositive.

amendments during the stay lifted just a month ago.

Second, the amendments will not unfairly prejudice Ravgen. Much of the evidence underlying the amendments is within Ravgen's possession—including because Ravgen is aware of these arguments from the *Quest* case. *See Cordance Corp. v. Amazon.com, Inc.*, 255 F.R.D. 366, 371, 373 (D. Del. 2009). Fact discovery is still in early stages. Accordingly, Ravgen cannot show that granting this Motion would: (1) require Ravgen to "expend significant additional resources to conduct discovery and prepare for trial"; (2) "significantly delay the resolution of the dispute"; or (3) "prevent [Ravgen] from bringing a timely action in another jurisdiction." *Cloud Farm Assocs., L.P. v. Volkswagen Grp. of Am., Inc.*, 2012 WL 3069390, at *2 (D. Del. July 27, 2012).

Third, Defendants bring this Motion based in part on facts that they have discovered and developed during the stay. The amendments are therefore brought in good faith.

Finally, the amendments are not futile. An amendment is only futile if "it is frivolous, fails to state a claim upon which relief can be granted, or 'advances a claim or defense that is legally insufficient on its face.'" *Cloud Farm*, 2012 WL 3069390, at *1. That is not the case here.

Inequitable Conduct. At the pleading stage, allegations of inequitable conduct must identify the "who, what, when, where and how" of the material misrepresentation or omission committed before the PTO. *Andrulis Pharms. Corp. v. Celgene Corp.*, No. 13-1644-RGA, 2015 WL 4366118, at *4 (D. Del. July 16, 2015). The amendments easily satisfy that standard. As to materiality, the amendments allege facts showing that the PTO would not have granted the patents absent Ravgen's "unexpected results" arguments, and that the withheld information calls into question the credibility of those arguments. *Supra* at 1-2. As to intent, the amendments allege facts showing that Drs. Dhallan and Cronin knew the withheld references were material (including because they undermined Ravgen's key argument for patentability and because others in the field informed them that they viewed disclosure of the contradictory results as important to assessing Ravgen's results) and that the only reasonable inference from the facts is that Drs. Dhallan and Cronin had a specific intent to deceive the PTO by failing to disclose them. *Supra* at 1-2. Indeed, this same evidence has survived a ***summary judgment*** challenge from Ravgen, and justified setting an early bench trial. *Supra* at 2. Ravgen appears to argue futility because IPR challengers disclosed the Chung and Chinnapapagari references in secondary considerations arguments to the PTAB, and those IPRs were unsuccessful. That argument is wrong. ***First***, the PTAB cannot and did not address inequitable conduct. ***Second***, the PTAB specifically stated that it did not reach the secondary considerations arguments that cited to Chung and Chinnapapagari. *E.g.*, Ex. 10, IPR2021-01272, Paper 50 at 56 n.34. ***Third***, the PTAB did not make any findings on the materiality of the Chung and Chinnapapagari references or Dr. Dhallan and Dr. Cronin's intent in failing to disclose them.

Contract Defenses. The contract-based amendments state a valid claim—particularly where another court has already ruled that the underlying agreement ***does grant*** a release. *See* Ex. 11, *Quest*, D.I. 449 at 7. Ravgen appears to assert futility because the summary judgment ruling in *Quest* was vacated due to settlement (Ex. 11, *Quest*, D.I. 492 at 1), and Ravgen later amended the Ravgen-TF PLA in an apparent attempt to eliminate the rights granted to third parties. But those efforts failed, including because the rights were "irrevocably" granted. Ex. 1 at 35; *see* Restatement (Second) of Contracts § 311. Ravgen's attempts to do so only confirm that the agreement released TF customers.

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Respectfully submitted,

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